

## REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed March 23, 2005 ("Office Action"). Claims 72, 74-110, 112, and 114-119 are pending in the application. No claims are amended. Applicant notes with appreciation the allowance of claims 77-79, 89, 93, and 100 as well as the indication of allowability of the subject matter of claim 102. Applicant respectfully requests reconsideration as to the rejection of claims 72, 74-76, 80-88, 90-92, 94-99, 101, 103-110, 112 and 114-119 for the following reasons.

### Anticipation -- 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Manual of Patent Examining Procedure § 2131 (8th ed., rev. 2, May 2004) (quoting Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)).

The Office Action rejects claims 72, 74-76, 82, 83, 90, 97, 101, 107, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,009,343 ("Shain").

Shain discloses the use of vacuum to enhance the transdermal transport of fluids in sampling methods for the detection of analytes in a patient's blood. See Abstract. According to Shain, "ultrasound is applied to a region of the skin, reduced pressure is applied to the same vicinity of the skin and any fluid which exudes the skin is collected." Shain, col. 2, ll. 20-24.

Independent claim 72 includes, among other limitations, the requirement of "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone." Shain fails to teach or suggest continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. To support its assertion that Shain teaches this limitation, the Office Action points to col. 3, ll. 14-24, which states the following:

Analysis element 22 is used to determine the presence or amount of at least one analyte of interest and the particular features of analysis element 22 are not critical to the invention. Thus, any analyte detection method, sensor, or system suitable for use with the analyte of interest, for example optical or electrochemical sensors known in the art, may be used in analysis element 22. An example of a suitable analysis device is an interference-free biosensor such as that described in U.S. patent application Ser. No. not yet available; Atty Docket Number 5843.US.01, filed Dec. 18, 1995).

The above-quoted passage does not teach "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone" and no other teaching of continuous determination or monitoring has been identified in the office action. Moreover, the use of an interference-free biosensor does not convert the process of Shain into a process involving "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone." Shain fails to teach each and every element of claim 72 and thus does not anticipate claim 72. Claims 74-76, 82, 83, 90, 97, and 101 are not anticipated as they depend from and incorporate the limitations of claim 72. Accordingly, the rejection of claims 72, 74-76, 82, 83, 90, 97, and 101 under 35 U.S.C. § 102(e) as being anticipated by Shain must be withdrawn.

Independent claim 107 includes, among other limitations, the requirement of "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." The Office Action again relies on col. 3, ll. 14-24 for a teaching of "a sensing device . . . for continuously measuring." As discussed above, nothing in Shain teaches or suggests "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." Shain fails to teach each and every element of claim 107 and thus does not anticipate claim 107. Claims 112 and 114 are not anticipated as they depend from and incorporate the limitations of claim 107. Accordingly, the rejection of claims 107, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by Shain must be withdrawn.

The Office Action rejects claims 72, 74-76, 80-86, 88, 90-92, 97, 98, 101, 107, 108, 112, 114, 117-119 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application No. 2002/0045850 ("Rowe").

Rowe teaches "ultrasound enhancement of transdermal transport" and a "two step noninvasive method involv[ing] application of ultrasound to increase skin permeability and removal of ultrasound followed by transdermal transport that can be further enhanced using a physical enhancer." See Abstract. Rowe teaches that "channeling of ultrasound geometrically," paragraph 14, as one way of enhancing ultrasound.

Independent claim 72 includes, among other limitations, the requirement of "continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone." Rowe fails to teach *continuously* determining as it is directed simply to

measurement of concentration. To support its assertion that Rowe teaches a step of "continuously determining," the Office Action points to paragraph 93 of Rowe, which states the following:

[0093] In the case of analyte extraction using either of the above-described means of focusing ultrasound, the amount of analyte extracted in the coupling medium is measured using appropriate assay methods. For example, an assay method which results in a color change could be used. The change in color could be detected using a light beam which enters into the disposable chamber through a window on top. The analyte may also be detected in the chamber through the use of an enzyme electrode or biosensor. An example of an enzyme electrode for glucose is a screen-printed electrode on the surface of which is immobilized glucose oxidase and an electron mediator such as ferrocene or its derivatives. Electrons generated by the oxidation of glucose are transferred from glucose oxidase to the electrode via the mediator. Thus, the concentration of glucose in the analyte solution is proportional to the current generated. Yet another detection mechanism may be used based on near-infrared spectroscopy. In this method, concentration of extracted glucose in the gel is detected by the absorption of the near-infrared light which passes through the chamber through two windows. The window through which the light passes may be separate from the ultrasound transducer or the beam may pass directly through the transducer.

However, the above-quoted passage does not teach "continuously determining" of anything. Instead, the above-quoted passage simply refers to methods of determining the concentration of glucose in an analyte solution. Measurement of glucose concentration in an analyte solution can be accomplished without continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. Thus, Rowe fails to teach each and every element of claim 72 and thus does not anticipate claim 72. Claims 74-76, 80-86, 88, 90-92, 97-98, and 101 are not anticipated as they depend from and incorporate the limitations of claim 72. Accordingly, the rejection of claims 72, 74-76, 80-86, 88, 90-92, 97-98, and 101 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

Independent claim 107 includes, among other limitations, the requirement of "a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid." The Office Action points to paragraph 93 to support its contention that Rowe

teaches a step of "continuously measuring." However, as discussed above with respect to a step of "continuously determining," Rowe does not include a step of continuously measuring. Instead, Rowe merely teaches measuring the concentration of glucose in an analyte solution. This can be accomplished without continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. Thus, Rowe fails to teach each and every element of claim 107 and thus does not anticipate claim 107. Claims 108, 112, and 114 are not anticipated as they depend from and incorporate the limitations of claim 107. Accordingly, the rejection of claims 107-108, 112, and 114 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

Independent claims 117 and 118 include, among other limitations, the requirement of "continuously monitoring a change in said at least one characteristic of said gel" and "a monitoring device for continuously monitoring a change in said at least one characteristic of said gel," respectively. The Office Action points to paragraph 93 to support its contention that Rowe teaches a step of "continuously monitoring." However, as discussed above with respect to a step of "continuously determining," Rowe does not include a step of continuously monitoring. Instead, Rowe merely teaches measuring the concentration of glucose in an analyte solution. This can be accomplished without continuously determining the quantity of at least one analyte in the body fluid in the sensing zone. Thus, Rowe fails to teach each and every element of either claim 117 or claim 118 and thus does not anticipate these claims. Claim 119 is not anticipated as it depends from and incorporates the limitations of claim 118. Accordingly, the rejection of claims 117-119 under 35 U.S.C. § 102(e) as being anticipated by Rowe must be withdrawn.

### **Statement of Common Ownership**

This application, Appln. No. 09/868,442, and Rowe (i.e., Appln. No. 09/861,924, later published as US 2002/0045850), were, at the time of filing of this application, commonly owned by or under an obligation of assignment to Sontra Medical, Inc. Pursuant to 35 U.S.C. § 103(c)(1), Rowe is unavailable as a reference against this application for purposes of obviousness under 35 U.S.C. § 103.

**Obviousness -- 35 U.S.C. § 103**

The Office Action rejects claim 87 under 35 U.S.C. § 103(a) as unpatentable over Rowe as applied to claim 86 above, further in view of U.S. Patent No. 6,468,229 ("Grace"). Rowe is relied on as a primary reference in the rejection of claim 87 under 35 U.S.C. § 103. As discussed above under the section entitled "Statement of Common Ownership," Rowe is unavailable as a reference against this application for purposes of obviousness under 35 U.S.C. § 103. Accordingly, the rejection of claim 87 under 35 U.S.C. § 103(a) as unpatentable over Rowe in view of Grace must be withdrawn.

The Office Action rejects claims 95 and 96 under 35 U.S.C. § 103(a) as unpatentable over Rowe as applied to claim 90 above, further in view of U.S. Patent No. 6,503,198 ("Aronowitz"). Rowe is relied on as a primary reference in the rejection of claims 95-96 under 35 U.S.C. § 103. As discussed above under the section entitled "Statement of Common Ownership," Rowe is unavailable as a reference against this application for purposes of obviousness under 35 U.S.C. § 103. Accordingly, the rejection of claims 95-96 under 35 U.S.C. § 103(a) as unpatentable over Rowe in view of Aronowitz must be withdrawn.

The Office Action rejects claim 99 under 35 U.S.C. § 103(a) as unpatentable over Rowe as applied to claim 86 above, further in view of WO 97/30749 ("Abbott"). Rowe is relied on as a primary reference in the rejection of claim 99 under 35 U.S.C. § 103. As discussed above under the section entitled "Statement of Common Ownership," Rowe is unavailable as a reference against this application for purposes of obviousness under 35 U.S.C. § 103. Accordingly, the rejection of claim 99 under 35 U.S.C. § 103(a) as unpatentable over Rowe in view of Abbott must be withdrawn.

The Office Action rejects claims 103-106, 109, 110, 115, and 116 under 35 U.S.C. § 103(a) as unpatentable over Rowe as applied to claims 72 and 107 above, further in view of U.S. Patent No. 5,722,397 ("Eppstein"). Rowe is relied on as a primary reference in the rejection of claims 103-106, 109, 110, 115, and 116 under 35 U.S.C. § 103. As discussed above under the section entitled "Statement of Common Ownership," Rowe is unavailable as a reference against this application for purposes of obviousness under 35 U.S.C. § 103. Accordingly, the rejection

of claims 103-106, 109, 110, 115, and 116 under 35 U.S.C. § 103(a) as unpatentable over Rowe in view of Eppstein must be withdrawn.

Applicant submits that this response addresses all of the issues raised in the Office Action. Applicant submits that claims 72, 74-110, 112, and 114-119 are in condition for allowance and notice to that effect is hereby solicited. Should any issues remain to be discussed in this application, the Examiner is invited to contact the undersigned by telephone.

In the event any variance exists between the amount authorized to be charge to the Deposit Account and the Patent Office charges for reconsideration of this application, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,  
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